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EXAMINER

LACOURCIERE, KAREN A

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1635

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

TECH CENTER 1600/2000

Paper No. 01292004

Application Number: 09/631,411
Filing Date: August 03, 2000
Appellant(s): CAO ET AL.

Benjamin Aaron Adler, Ph.D., J.D.
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed November 24, 2003.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

No amendment after final has been filed.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

Appellant's brief presents arguments relating to an objection to the specification based on improper incorporation by reference. This issue relates to petitionable subject

matter under 37 CFR 1.181 and not to appealable subject matter. See MPEP § 1002 and § 1201.

(7) *Grouping of Claims*

The rejection of claims 11-14 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record

set forth in the prior Office action, mailed June 3, 2003. This is a written description rejection.

Claims 11-14 are drawn to methods of screening for a compound that disrupts transcriptional repression of a gene wherein a Smad6/Hoxc-8 protein complex is formed. The specification as filed does not provide any structural information, i.e. sequence, for Smad6 or Hoxc-8 such that the skilled artisan would recognize the common structural features of proteins encompassed in the terms Smad6 and Hoxc-8. It is noted that the specification incorporates by reference publications that include sequences for Smad6 and Hoxc-8 (see page 31 of the specification), however, incorporation by reference of "essential material", i.e. the structural information required to describe the claimed invention in this case, may not be incorporated by reference to non-patent publications. (see MPEP 608.01(p)).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-14 are maintained as rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record set forth in the prior Office action, mailed June 3, 2003.

Claims 11-14 are indefinite due to the recitation "Smad6" and "Hoxc-8", because the specification has not provided a definition for what proteins would be encompassed in these terms, or enough information on the structure of these proteins, such that the

skilled artisan would know what proteins are encompassed in these terms. For example, the prior art recognized some proteins that would be encompassed by the terms "Smad6" and "Hoxc-8", because these names are used in the prior art, however, it is unclear what other proteins would be encompassed in these terms because the names assigned to proteins are not necessarily used consistently in the art. For example, what proteins would be encompassed by these terms, but referred to in the prior art by an alternative name? The specification has not provided enough structural information or characteristics of "Smad6" or "Hoxc-8" proteins such that the skilled artisan could determine what proteins are encompassed in the claims, but referred to using an alternative name.

(11) *Response to Argument*

Applicant has provided arguments to traverse the objection to the specification of record, however, these arguments have not been addressed herein because this issue relates to petitionable subject matter under 37 CFR 1.181 and not to appealable subject matter. Similar arguments were addressed in the prior Office action, mailed June 3, 2003.

Applicant's arguments filed November 24, 2003 directed to the rejections of record of claims 11-14 under 35 USC 112, first and second paragraphs have been fully considered but they are not persuasive.

In response to the rejection of record of claims 11-14 under 35 USC 112, first paragraph, as lacking adequate written description, Applicant argues that The specification has provided sufficient written description for the claimed invention and demonstrates possession of the invention by reduction to practice.

Applicant argues data in the specification demonstrates the interaction of Smad6 and Hoxc-8 by a yeast two-hybrid screen and co-immunoprecipitation in cell assays, gel-shift assays and interference with Smad1/Hoxc-8 interactions. Applicant argues that Smad6 and Hoxc-8 proteins are well known in the art and the skilled artisan would readily recognize these proteins based on the description disclosed in the specification. Applicant argues that the specification describes Smads as proteins that mediate signaling in the superfamily of TGF- β and that the subgroup of Smad6 and Smad7 antagonize signaling of TGF- β and form stable associations with activated type I receptors. Applicant argues that the specification describes that there are 39 Hox homeobox-containing transcription factor genes in vertebrates, which play critical roles in embryonic development. The 39 Hox genes are divided into 13 paralogous groups, including group VIII, which includes three members, one of which is Hoxc-8, shown by Northern Blot to be expressed during human embryo development in high levels in the spinal cord, backbone and limbs and at a lower level in the heart. Based on this description, Applicant argues the skilled artisan would readily recognize what Smad6 and Hoxc-8 and would not confuse the identity of these proteins.

These arguments have not been found to be persuasive because the description of Smad6 and Hoxc-8 in the specification does not provide any structural information for

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Smad6 or Hoxc-8 such that the skilled artisan would recognize the common structural features of proteins encompassed in the terms Smad6 and Hoxc-8. Applicant asserts that these proteins are so well known in the art that the skilled artisan would recognize these proteins, however, Applicant has not provided any evidence to support their assertion. Applicant discusses the description of Smad6 and Hoxc-8 in the specification, however, this description is not sufficient to demonstrate possession of the claimed invention. The description of Smad6 and Hoxc-8 in the specification discusses some activities of these proteins, but does not provide any structural information about the proteins. The activities described in the specification for these proteins are non-specific and vague and the activities are ascribed to a large group of proteins, rather than the specific proteins Smad6 and Hoxc-8. For example, Smads are described as proteins that mediate TGF- β signaling, but this activity applies to all Smads and does not particularly describe Smad6. Additionally, Smad6 and Smad7 are thought to interact with type I receptors, however, this is not unique to Smad6, as the description applies equally to Smad7 proteins. The description is not sufficient to describe the common structural elements of Smad6 proteins to describe the genus of Smad6 proteins required for the claimed methods. For Hoxc-8, the description identifies Hoxc-8 as a member of a paralog group within a larger group of 39 genes, but this description provides no information about the structure of the genus of Hoxc-8 proteins required for the claimed methods. Although the specification provides some information on the broad genus of Hox proteins in embryonic development, the description is not unique to Hoxc-8 and does not specifically describe Hoxc-8. The specification discusses the

expression pattern of one species of Hoxc-8, human, in embryonic development; however, this does not provide any structural information on the broad genus of Hoxc-8 proteins required in the claimed methods. The specification provides no structural information to describe Smad6 proteins or Hoxc-8 proteins and the information on the activity of Smad6 and Hoxc-8 is general and applies to the broader family of proteins to which Smad6 and Hoxc-8 belong, for example, they do not describe the characteristics of Smad6 proteins that differ from Smad7 or how Hoxc-8 differs from other Group VII Hox proteins such as Hoxb-8 or Hoxd-8.

Contrary to Applicant's arguments, the specification does not appear to reduce to practice the claimed invention, which is directed to a method for screening for a compound that disrupts transcriptional repression of a gene, wherein Smad6/Hoxc-8 complex is combined with the gene in the presence and absence of a compound and transcription of the gene is assayed to observe a decrease in transcriptional repression. The examples in the specification Applicant relies upon in the arguments do not reduce this method to practice, as the examples are directed to methods which determine Smad6/Hoxc-8 binding and one transcription assay that determines Smad1 transcriptional activation in the presence and absence of the Smad6/Hoxc-8 protein. The specification does not reduce to practice any method wherein a compound is screened to determine if the compound disrupts transcriptional repression wherein gene transcription is assayed in the presence of Smad6/Hoxc-8 and in the presence and absence of a compound. Additionally, the examples in the specification do not provide any structural information on the genus of Smad6 and Hoxc-8 proteins required to

practice the claimed methods. For example, although the examples provide gels, there are not even molecular weight markers on these gels by which the skilled artisan could determine the molecular weight of Smad6 or Hoxc-8.


In response to the rejection of record of claims 11-14 under 35 USC 112, second paragraph, Applicant argues that Smad6 and Hoxc-8 are well-known and extensively studied proteins in the art, that the skilled artisan would readily recognize what Smad6 and Hoxc-8 proteins are and are unlikely to be confused as to their identity.

These arguments have not been found to be persuasive because the terms "Smad6" and "Hoxc-8" are simply names and do not provide a limiting definition for a protein by that name. The specification has not provided sufficient structural information or a description of physical characteristics for these proteins such that the skilled artisan could determine what proteins are encompassed in the scope of proteins used in the claimed methods. The descriptions of these proteins are non-specific and it is unclear how these specific proteins are even distinguished from other members of the same protein family. Because the description of these proteins is insufficient, it is not possible to determine if these proteins are named differently in the art, because there is insufficient description by which to search for these proteins. Applicant has not provided any evidence to support their assertion that these proteins are so well known in the art that there would not be any confusion as to the identity of the proteins.

For the above reasons, it is believed that the rejections should be sustained.


Respectfully submitted,

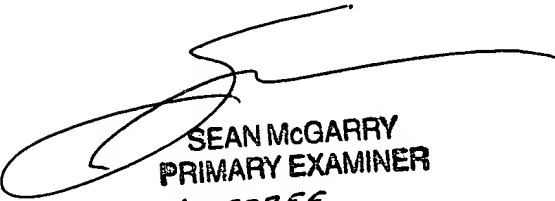
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February 4, 2004


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